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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,814	09/04/2002	Andrew Austen Mortlock	Z70599-1P US	2356
44992 7590 03/14/2008 ASTRAZENECA R&D BOSTON 35 GATEHOUSE DRIVE WALTHAM, MA 02451-1215				
EXAMINER				
TRUONG, TAMTHOM NGO				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/088,814

Applicant(s)

MORTLOCK ET AL.

Examiner

TAMTHOM N. TRUONG

Art Unit

1624

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20, 27, 30, 34-39 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 27, 30, 34-39 and 41-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

FINAL ACTION

Applicant's amendment of 12-12-07 has been fully considered. The amended claims and argument have overcome the previous rejections of 112/1st and 2nd paragraphs, and thus, said rejections are now withdrawn. However, the amended claims have not overcome the previous 103 based on Brown et. al. Also, the amended claim 20 raises new matter.

Claims 1-19, 21-26, 28, 29, 31-33 and 40 are cancelled.

Claims 20, 27, 30, 34-39 and 41-44 are pending.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **New Matter:** Claims 20, 27, 30, 34-39 and 41-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 20 has been amended to recite "aryl" in place of "aroyl", "aralkyl" in place of "arC₁₋₁₀alkyl", and "aralkyloxy" in place of "arC₁₋₁₀alkyloxy". The terms "aralkyl" and "aralkyloxy" have a broader range of C atoms. Since there is no definition of said terms, they could encompass heterocycles and raise new matter. The term "aryl"

suggests an aromatic ring while the term “aroyl” suggests “ring-C(=O)-”. Thus, those two terms are not the equivalent of each other, and therefore, raise new matter as well.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 20, 27, 30, 34-39 and 41-44 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 recites the definition for R^3 , but formula (IID) had R^3 instead. It is believed that this is a typographical error. Applicant is requested to correct it promptly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 20, 27, 30, 34-39 and 41-44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over **Brown et. al.** (cited previously). The rejection is maintained for the reason

stated previously. Applicant argued that the exclusion of $\text{CH}_3\text{O}-$ at the 7-position (or $\text{R}^{3'}$) has overcome the teaching of Brown's compound in Example 11. However, the exclusion of one species does not sufficiently overcome the equivalency teaching of Brown for $-\text{CONH}-$ vs. $-\text{NHCO}-$ as defined for variable X in the reference and other substituents as defined for R^1 (see page 27). Furthermore, Brown also teaches various groups at the 7-position (corresponding to the instant $\text{R}^{3'}$) which is **not** a $\text{CH}_3\text{O}-$. For example, on page 27, see the preferred substituents represented by R^1 . Note, the list also includes **3-morpholinopropoxy**, which would make applicant's Example 101 falls within the preferred embodiment of Brown et. al. In another place like Example 19 (on page 81), the 7-position is **2-methoxyethoxy**, which is a group falls within the instant $-\text{X}^1\text{R}^{15}$. The fact that Brown does not show an activity for the compound in Example 11 does not mean there is no activity for said compound.

Applicants cited the case law of Takeda Chemical Industries, LTD v. Alphapharm PTY, LTD. to support the argument of lacking motivation for a prima facie obviousness. However, in Takeda's case, the prior art compound was documented in more than one reference and by expert witnesses as having serious side-effects that would be deleterious for its intended purpose. There is no such evidence herein. Additionally, the "lead" prior art compound in Takeda was not particularly singled out for its activity in the reference relied on by the examiner, which the Court stated "discloses hundred of millions of TZD compounds".

It is further noted that the Court in Takeda relied on the unexpectedly superior properties of appealed compound over compound b. Thus, given the totality of the facts in Takeda, the

decision rendered was based on “reasonable expectation” of success in performing the intended use, which in that case led to disqualification of the prior art compound.

In the instant case, Brown’s preferred embodiment (on page 27) is directed to a very narrow scope of compounds in which X represents only a few functional groups including NHCO , and substituents for the 7-position fall within the scope of the instant $-\text{X}^1\text{R}^{15}$ which is not a $\text{CH}_3\text{O}-$. Thus, given a finite number of compounds in the preferred embodiment of Brown for modification, and the need to find more selective receptor tyrosine kinase inhibitor, the examiner believes that the burden set forth in the KSR decision has been met.

In addition, the MPEP 2141.02 (VI) states that alternative embodiments should not be confused with “teaching away” citing a recent decision, **In re Fulton** (73 USPQ 2d 1141). Note, the following passage in *Fulton* on page 1146: *“The prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed in the ‘198 application. Indeed, in the case cited by appellants, In re Gurley, we held that the invention claimed in the patent application was unpatentable based primarily on a prior art reference that disclosed two alternatives, one of which was the claimed alternatives. Accordingly, mere disclosure of alternative designs does not teach away”*.

Therefore, it is maintained that Brown’s preferred embodiment provides a finite set of compounds which embraces permutations (at the 7-position) claimed herein. Thus, Brown provides sufficient motivation for a prima facie obviousness to modify the compound in Example 11 to obtain compounds of the instant formula (IID) wherein $\text{R}^{3'}$ is not a $\text{CH}_3\text{O}-$ group.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **TAMTHOM N. TRUONG** whose telephone number is (571)272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tamthom N. Truong/

Tamthom N. Truong
Examiner
Art Unit 1624

2-28-08

/James O. Wilson/
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